

REMARKS

Applicant has received and carefully reviewed the Office Action of the Examiner mailed September 7, 2006. Currently, claims 1-25 remain pending. In this amendment, claims 1, 11-12, 17-19, and 23 have been amended and claims 16 and 20-21 have been canceled. Favorable consideration of the following remarks is respectfully requested.

Rejections under 35 U.S.C. § 102

In paragraph 3 of the Office Action, claims 1, 12-13, 15, 23 and 25 were rejected under 35 U.S.C. §102(b) as being anticipated by Mueller, Jr. (US 4,938,220). Turning to claim 1, which recites:

1. A medical device, comprising:
 - a tubular member having a proximal end region and a distal end region;
 - a radiopaque marker band disposed over the tubular member, the marker band having an outer surface and an inner surface with one or more openings through the outer surface of the marker band; and
 - an outer layer disposed over the outer surface of the marker band, wherein the outer layer extends from the outer surface of the marker band into the openings in the marker band and fills the openings.

As amended, claim 1 recites, “an outer layer disposed over the outer surface of the marker band, wherein the outer layer extends from the outer surface of the maker band into the openings in the marker band and fills the openings.” As amended, claim 1 is believed to be allowable over Mueller, Jr.

The Office Action states that Mueller, Jr. teaches a radiopaque marker band (10) having a gap (12), the marker band (10) being positioned on a tubular member (16), and an outer layer (19) positioned over the tubular member (16). However, in contrast to claim 1, Mueller Jr. also teaches a vent opening 24 extending through the gap (12) of the marker band (10). Mueller Jr. recites:

A small vent opening 24 extends longitudinally between the distal end portion of the balloon and the distal end of the catheter to permit trapped gases to be evacuated from the balloon. This opening is of a size large enough to pass the gas molecules but small enough to prevent the passage of liquid. This opening typically has a diameter on the order of 0.0006 inch, and in the embodiment illustrated, it is formed at the junction of tubular members 16, 19. (Column 2, lines 17-25, emphasis added.)

A second marker 26 is mounted on inner tubular member 16 toward the midpoint of balloon 18. This marker comprises a band of radiopaque material such as gold. In a preferred method of manufacture, the split tip marker sleeve 11 is positioned near the distal end of inner tubular member 16 and crimped about that member to hold it in position temporarily. Marker 26 is positioned on the inner tubular member and affixed by suitable means such as cementing. *A longitudinally extending mandrel such as a tungsten wire (not shown) is temporarily affixed to the outer surface of tubular member between the confronting edges of sleeve 11 to form vent opening 24.* The outer tubular member 19 is then positioned over the inner tubular member, and the distal end portions of the tubular members are bonded together by heat sealing to close the distal end of the balloon and to capture the tip marker sleeve between the members. *The tungsten wire mandrel is then removed to form the vent opening.*

Operation and use of the catheter are as follows. The catheter is positioned in the vascular system of a patient over a guide wire (not shown) which passes through lumen 17. The position of the tip of the catheter and the balloon can be observed fluoroscopically by means of markers 10, 26. Pressurized fluid is introduced into balloon 18 through annular passageway 22 to inflate the balloon, *with any gas trapped in the balloon being expelled through vent opening 24.* (Column 2, lines 31-68, emphasis added.)

Therefore, by incorporating a vent opening (24) into the medical device, the outer layer (19) does not fill the opening in the marker band. Accordingly, Mueller Jr. does not teach or suggest “an outer layer disposed over the outer surface of the marker band, wherein the outer layer extends from the outer surface of the marker band into the openings in the marker band and fills the openings,” as recited in amended claim 1, but in contrast, teaches an outer layer having a vent. Furthermore, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” (*Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). Therefore, Mueller Jr. does not anticipate claim 1 because Mueller Jr. does not teach each and every element set forth in the claim. Thus, for reasons given above, as well as others, claim 1 is believed to be allowable over Mueller Jr., and Applicant respectfully requests withdrawal of the rejection.

Turning to claim 12, which recites:

12. A medical device, comprising:
 - an elongate core member having a proximal end region and a distal end region;
 - a radiopaque marker band disposed over the core member, the marker band having one or more slits defined therein, the marker band having an inner surface and an outer surface; and

a coating disposed over the outer surface marker band, wherein the coating extends from the outer surface of the marker band toward the core member and fills the one or more slits of the marker band.

As amended, claim 12 recites, “a coating disposed over the outer surface marker band, wherein the coating extends from the outer surface of the marker band towards the core member and fills the one or more slits of the marker band.” As discussed previously, nowhere does Mueller Jr. teach or disclose this limitation. Therefore, for similar reasons given above, as well as others, claim 12 is believed to be allowable over Mueller Jr., and Applicant respectfully requests withdrawal of the rejection.

Additionally, for similar reasons, as well as others, claims 13 and 15, which depend from claim 12 and include significant additional limitations, are believed to be allowable over Mueller Jr., and Applicant respectfully requests withdrawal of the rejection.

Turning to claim 23, which recites:

23. A guide catheter comprising:
an inner tubular member having a proximal region and a distal region;
a radiopaque marker band disposed over a portion of the inner tubular member at a selected location in the distal region, the radiopaque marker having an inner surface and an outer surface with at least one opening extending from the inner surface to the outer surface; and
an outer layer extending over the marker band and at least a portion of the inner tubular member, wherein a portion of the outer layer extends through the at least one opening and is in contact with the inner tubular member and fills the at least one opening.

As amended, claim 23 recites, “an outer layer extending over the marker band and at least a portion of the inner tubular member, wherein a portion of the outer layer extends through the at least one opening and is in contact with the inner tubular member and fills the at least one opening.” As discussed previously, nowhere does Mueller Jr. teach or disclose this limitation. Therefore, for similar reasons given above, as well as others, claim 23 is believed to be allowable over Mueller Jr., and Applicant respectfully requests withdrawal of the rejection.

Additionally, for similar reasons, as well as others, claim 25, which depends from claim 23 and includes significant additional limitations, is believed to be allowable over Mueller Jr., and Applicant respectfully requests withdrawal of the rejection.

In paragraph 6 of the Office Action, claim 16 was rejected under 35 U.S.C. §102(e) as being anticipated by Nutting et al. (US 6,733,489). Applicant has canceled claim 16, thereby rendering the rejection moot.

Rejections under 35 U.S.C. § 103

In paragraph 11 of the Office Action, claims 2-7 were rejected under 35 U.S.C. §103(a) as being unpatentable over Mueller, Jr. in view of Nutting. For similar reasons given above, as well as others, claims 2-7, which depend from claim 1 and include significant additional limitations, are believed to be allowable over Mueller Jr. in view of Nutting et al., and Applicant respectfully requests withdrawal of the rejection.

In paragraph 18 of the Office Action, claims 8-10 were rejected under 35 U.S.C. §103(a) as being unpatentable over Mueller, Jr. in view of McBroom et al. (US 6,227,108). For similar reasons given above, as well as others, claims 8-10, which depend from claim 1 and include significant additional limitations, are believed to be allowable over Mueller Jr. in view of McBroom et al., and Applicant respectfully requests withdrawal of the rejection.

In paragraph 23 of the Office Action, claim 11 was rejected under 35 U.S.C. §103(a) as being unpatentable over Mueller, Jr. in view of Eidenschink et al. (US 6,970,734).

- 11. A medical device, comprising:
 - a tubular member having a proximal end region and a distal end region;
 - a radiopaque marker band disposed over the tubular member, the marker band having an outer surface and an inner surface with one or more openings through the outer surface of the marker band;
 - an outer layer disposed over the outer surface of the marker band, wherein the outer layer extends from the outer surface of the marker band, into the openings in the marker band filling the one or more openings; and
 - wherein the tubular member includes an outer surface, and wherein the outer surface is defined by a fluorocarbon polymer.

The Office Action states, “Mueller, Jr. discloses a medical device comprising a tubular member (16); a radiopaque marker band (10) with an inner surface (not referenced), an outer surface (not referenced) and an opening (12); and an outer layer (19). (See Figure 2)”. The Office Action continues to state that Mueller, Jr. fails to disclose an outer surface defined by a fluorocarbon polymer and that Eidenschink et al. “teaches a catheter defined by a fluorocarbon

polymer such as polytetrafluoroethylene.” The Office Action goes on to state that it would have been obvious to combine the fluorocarbon to manufacture the medical device of Mueller, Jr.

However, as amended, claim 11 recites, “an outer layer disposed over the outer surface of the marker band, wherein the outer layer extends from the outer surface of the marker band, into the openings in the marker band filling the one or more openings”. As discussed previously, nowhere does Mueller Jr. disclose this limitation. Furthermore, nowhere do Eidenschink et al. remedy the shortcomings of Mueller, Jr. Therefore, for similar reasons given above, as well as other reasons, claim 11 is believed to be allowable over Mueller Jr. in view of Eidenschink et al., and Applicant respectfully requests withdrawal of the rejection.

In paragraph 28 of the Office Action, claim 14 was rejected under 35 U.S.C. §103(a) as being unpatentable over Mueller, Jr. in view of Eidenschink et al. further in view of Hopkins (US 5,948,489). For similar reasons given above, as well as others, claim 14, which depends from claim 11 and includes significant additional limitations, is believed to be allowable over Mueller Jr. in view of Eidenschink et al. further in view of Hopkins, and Applicant respectfully requests withdrawal of the rejection.

In paragraph 36 of the Office Action, claims 17-19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Nutting et al. in view of McBroom et al.

Turning to claim 17, which recites:

17. A radiopaque marker band adapted for being secured to an intravascular medical device, comprising:

a generally cylindrical body section, the body section having a first slot and a second slot defined therein;

wherein the first slot and the second slot are axially aligned on opposing sides of body section; and

wherein the body section includes a proximal end and a distal end, and wherein the body section includes one or more slits in the proximal end, the distal end, or both.

The Office Action states that Nutting et al. disclose a marker band with a circular hole and with two slots, having one configuration with the slots aligned on either side of the marker band, or, in another configuration, with the slots offset on either side of the marker band. The Office Action continues to state that McBroom et al. teach a marker band comprising slits in the proximal and distal end regions of the marker band. (See Figures 6 and 7.)

However, as amended, claim 17 now recites, “the body section includes a proximal end and a distal end, and wherein the body section includes one or more slits in the *proximal end*, the *distal end*, or both.” Nowhere do McBroom et al. teach slits in the proximal end or the distal end of the generally cylindrical body.

In contrast, McBroom et al. teach a body with perforations 512 in the body that extend between the top surface 508 and the bottom surface 510 of the body. (See Figure 6 of McBroom et al.) From review of both the Figures (specifically Figures 6 and 7) and the corresponding description, McBroom et al. do not teach or suggest one or more perforations, or slits, in the top surface 508 or the bottom surface 510. Therefore, for reasons given above, as well as others, claim 17 is believed to be allowable over Nutting et al. in view of McBroom et al., and Applicant respectfully requests withdrawal of the rejection.

Turning to claims 18 and 19, which recite:

18. The marker band of claim 17, wherein the slits are defined in the proximal end and the distal end, and wherein the slits in the proximal end—are aligned with the slits in the distal end.

19. The medical device of claim 17, wherein the slits are defined in the proximal end and the distal end, and wherein the slits in the proximal end are staggered relative to the slits in the distal end.

For similar reasons given above, as well as others, claims 18 and 19, which depend from claim 17 and include significant additional limitations, are believed to be allowable over Nutting et al. in view of McBroom et al., and Applicant respectfully requests withdrawal of the rejection.

In paragraph 41 of the Office Action, claims 20 and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Rosenthal et al. (US 6,285,903) in view of Nutting et al. Applicant has canceled claims 20 and 21, thereby rendering the rejection moot.

In paragraph 46 of the Office Action, claim 22 was rejected under 35 U.S.C. §103(a) as being unpatentable over Crawford et al. (US 6,923,822) in view of Nutting et al. After careful review, Applicant respectfully disagrees. Claim 22 recites:

22. A method for manufacturing a medical device, comprising the steps of:
providing an elongate core member;
disposing a marker band over the core member, the marker band having one or more slots defined therein, a top surface, and a bottom surface;
disposing a coating over the core member and the marker band; and

wherein the step of disposing a coating over the core member and the marker band includes disposing the coating on the top surface of the marker band, within the slots, and along the bottom surface of the marker band between the marker band and the core member.

Specifically, claim 22 states, “disposing a coating over the core member *and* the marker band” and “wherein the step of disposing a coating over the core member *and* the marker band includes disposing the coating *on the top surface of the marker band, within the slots, and along the bottom surface of the marker band* between the marker band and the core member.” Applicant respectfully asserts that Crawford et al. do not teach this.

The Office Action states that “Crawford et al. discloses a method of securing a maker band to a balloon catheter comprising the steps of: providing a catheter, disposing a marker band over the catheter, and spray coating the marker band. (See Column 9 Lines 9-12).” The Office Action continues to state, “Crawford et al. fails to disclose a maker band comprising slots” and “Nutting et al. teaches a marker band with a circular hole and with two slots.” In one configuration the slots are aligned on either side of the marker band. In another configuration the slots are offset on either side of the marker band.” However, Applicant respectfully disagrees that neither Crawford et al. nor Nutting et al. disclose disposing a coating over the core member *and the marker band*, as recited in claim 22. The Examiner cites column 9, lines 9-12 of Crawford et al., which recites:

Preferably, the *marker bands* are integrally formed upon the diameter of the elongated body through the use of spray coating, electroplating or similar methods which will deposit the marker band material upon the elongated body. (Emphasis added.)

This does not teach or disclose disposing a coating over the core member and the marker band, but only teaches disposing a marker band over a core member with the use of spray coating, electroplating, or similar methods. Additionally, nowhere else do Crawford et al. disclose disposing a coating over a marker band. Furthermore, as shown in Figures 2-5, there is no coating disposed over the marker bands. Therefore, for reasons given above, as well as others, claim 22 is believed to be allowable over Crawford et al. in view of Nutting et al., and Applicant respectfully requests withdrawal of the rejection.

In paragraph 51 of the Office Action, claim 24 was rejected under 35 U.S.C. §103(a) as being unpatentable over Mueller, Jr. in view of Nebergall et al. (US 4,419,095). For similar

reasons, as well as others, claim 24, which depends from claim 23 and includes significant additional limitations, is believed to be allowable over Mueller Jr. in view of Nebergall et al., and Applicant respectfully requests withdrawal of the rejection.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

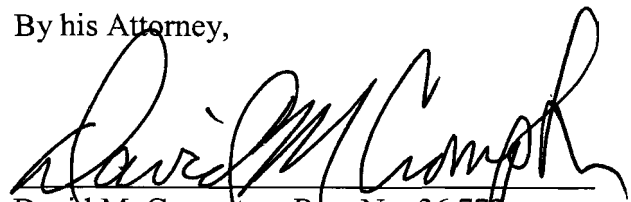
Respectfully submitted,

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By his Attorney,

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